Air*Life*® nCPAP System

Operator's & Routine Maintenance Manual
Driver Model 006900
Firmware Version 2.02

Latex Free

Cardinal Health
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Product Description

The Air*Life*® nCPAP System Driver is intended to provide continuous positive airway pressure (CPAP) for use in hospitals to treat spontaneously breathing newborns and infants with Respiratory Distress Syndrome (RDS), or are recovering from RDS under the supervision of qualified personnel (e.g., respiratory therapist or nurse). The driver operates on hospital or tank air, and oxygen. The device has an internal battery and can be used for intra-hospital transport, but is not intended for use in ambulances or aircraft.

The Air*Life*® nCPAP System Driver incorporates an electronic blender using solenoid valves and servo controlled flow to maintain a user-set pressure and FiO_2. The system also utilizes a long-life oxygen sensor. The user interface displays oxygen concentration, CPAP level, flow rate, trending, and power and alarm conditions. The oxygen sensor automatically calibrates every time the instrument is powered on. The driver is part of a larger system that includes an nCPAP generator, fixation device, and patient interface (prongs and/or masks).

Product Specification

Gas Supply

41–66 psig (nominal 50 psig) clean, dry, medical air and oxygen. External pressure regulators should be used if source pressures exceed 66 psig.

Pressure Control / Monitoring

Control Range: 2–10 cmH_2O
Monitor Range: 1–11 cmH_2O, accuracy ±1 cmH_2O. Pressure is displayed as <1 or >11 when outside this range.

Oxygen Control / Monitor

Control/Display Range: 21%–100% O_2, accuracy ±3 percentage points
Monitor Range: 17%–104%O_2, accuracy ±3 percentage points
Sensor Type: Long Life Ultrasonic (5+ years)

Flow Monitoring

Range: 0–15 LPM, accuracy ±10%

Power Supply

15 V DC, 3.3 A from included AC adapter (GlobTek, Inc. Model number GTM21097-5015) or an internal 12 V sealed lead/acid battery. The battery has a life of four (4) hours from a full charge (up to 16 hours required for recharge).

Weight

Approx. 15 pounds

Dimensions

8 ½ x 8 ½ x 6 ½ inches (excluding gas inlets, patient outlets, and mounting brackets)

Pressure Relief (2 systems)

Automatic electronic valve system preset to vent to ambient air when a High Pressure alarm occurs

Mechanical internal relief valve preset to vent at 3 ±0.15 psig (211 ±11 cmH_2O)

Flow Limit

Electronic flow limit to prevent the delivery flow from exceeding 3 LPM over Target Flow or 15 LPM.

Alarm System

Alarms are delayed for 120 seconds after entering the main screen in order to allow time for patient setup. If the patient setup takes longer than 120 seconds, the alarms can be muted for an additional 120 seconds by pressing the alarm mute/reset button or the system can be placed into Standby Mode.

Supply Gas Pressure Alarm: An audible and visual Source Pressure alarm will activate if the inlet pressure of one, or both, of the gas sources are outside of the specified gas supply range. There is a 1 second delay for this alarm. The alarm message will indicate the specific gas source that is out of specification. If a single gas source goes out of range during operation, then only the remaining gas source will be available (air or oxygen) and FiO_2 blending will become inoperable. The user will be able to select either 'Air Only' or 'Oxygen Only' to allow the unit to operate in single-gas source mode and mute the FiO_2 alarms while the problem is corrected. The system will automatically return to normal operation (blending to the original FiO_2 setting) when the problem is corrected and the source pressures are returned to within the specified range.

High Pressure Alarm: An audible and visual High Pressure alarm has dual limits. The first limit will activate the alarm when the monitored pressure is greater than or equal to 12 cmH_2O for 2 seconds. The second limit will activate the alarm immediately when the monitored pressure is greater than or equal to 18 cmH_2O. This alarm automatically activates the electronic pressure relief solenoid and closes the patient delivery solenoid, which instantly reduces the pressure in the patient circuit to zero. Approximately every three (3) seconds, the system will reinstate flow. If the alarm condition has cleared, the unit will operate normally. If the alarm condition still exists, the 'High Pressure' alarm will cycle through the 3-second loop.

Elevated Pressure Alarm: An audible and visual Elevated Pressure alarm is preset for a CPAP pressure that is 2 cmH_2O above the Set CPAP level. There is a 5 second delay for this alarm

Low Pressure Alarm: An audible and visual Low Pressure alarm is preset for a CPAP pressure that is 2 cmH_2O below the Set CPAP level. There is a 14 second delay for this alarm.

Disconnect Alarm: An audible and visual 'Disconnect' alarm is preset to detect a pressure line or patient interface that has come loose or that is disconnected. The alarm is set to activate according to the following list:

Flow (LPM)	CPAP (cmH_2O)
≥ 0	≤ 1
≥ 6	≤ 2
≥ 9	≤ 3
≥ 12	≤ 4
≥ 14	≤ 5

While the alarm is active, the patient flow will remain within ±2 LPM of Target Flow. There is a 5 second delay for this alarm.

Leak Alarm: An audible and visual Leak alarm is preset for a flow rate that is 3 LPM above the Target Flow rate or for a flow that is greater than 15 LPM. There is a 5 second delay for this alarm

Low Flow Alarm: An audible and visual Low Flow alarm is preset for flow rates at or below 3 LPM. There is a 10 second delay for this alarm.

Oxygen Concentration Alarms: The oxygen concentration is allowed to operate within a ±3 $\%O_2$ range without alarming.

A Medium Priority warning will activate whenever the product of the variance outside of the FiO_2 range and the duration (in seconds) of the variance exceeds 20.

A High Priority alarm will activate whenever the product of the variance outside of the FiO_2 range and the duration (in seconds) of the variance exceeds 30.

For example: if the Set $\%O_2$ is 30% and the reading is 35% for a period of ten (10) seconds, a Medium Priority warning will activate. In this case the reading is 2 percentage points outside of the ±3 percentage point range. If the Set $\%O_2$ is 30% and the reading is 35% for a period of 15 seconds, a High Priority alarm will activate.

Battery Alarms: An audible and visual Low Battery alarm has dual limits. The first limit will activate the medium priority alarm when the battery falls below 10% remaining (approx. 24 minutes). The second limit will activate the high priority alarm when the battery falls below 5% remaining (approx. 12 minutes). There is a 2 second delay for this alarm. An audible and visual Charge Fault alarm will indicate if the battery is not charging properly. The system verifies proper charging at start up and during the routine oxygen calibration. There is a 5 second delay for this alarm.

Oxygen Calibration Alarm: An audible and visual Oxygen Calibration alarm will indicate if an oxygen sensor has failed to calibrate. If this alarm occurs, remove patient and cycle the power for re-calibration or remove the driver from service. While the alarm is active, the driver provides CPAP and FiO_2, however, the FiO_2 may not be accurate. The system calibrates the oxygen sensor during start up and routinely during operation. There is no delay for this alarm

Software Fault: An audible and visual Software Fault alarm will indicate any software fault detected. The system will display a fault code which should be recorded. If the fault is non-fatal, the alarm can be cleared and the system will return to normal operation. If the fault is fatal, the driver will need to have the power cycled or be removed from service. There is no delay for this alarm

Flow / Pressure Sensor: A visual Sensor Calibration Fault will indicate if a sensor has failed the calibration during the start up routine. A failure screen will appear indicating what sensor has failed and informing the user to remove the device from service.

IEC 60601-1 Classification

Internally Powered Equipment, Type BF, IPX 1
This equipment is rated for Continuous Operation.

Caution: Although the Air*Life*® nCPAP System Driver meets the requirements of current EMC/RFI legislation, this does not guarantee immunity from all sources of radiated energy. Some mobile telephones and other products containing radio transmitting components may cause a malfunction of the Air*Life*® nCPAP driver and should not be used in the vicinity of the driver.

Storage and Operating Conditions

- ***Safe for storage at -20°C–60°C***
- ***Relative humidity of 15%–95% non-condensing***
- ***Atmospheric pressure 0.6–1.4 Bar.***
- ***Operating environment temperature is 5°C–40°C***
- ***Keep dry and do not expose to direct sunlight***
- ***This product meets the EMC requirements of IEC60601-1***

Warning: The patient accessories for use with the* Air*Life*® *nCPAP Driver are for single patient use only. Disposable accessories include generators, fixation device, prongs, masks, heated wire breathing circuits, and humidification chambers. DO NOT STERILIZE OR REUSE.

Driver Feature Diagrams

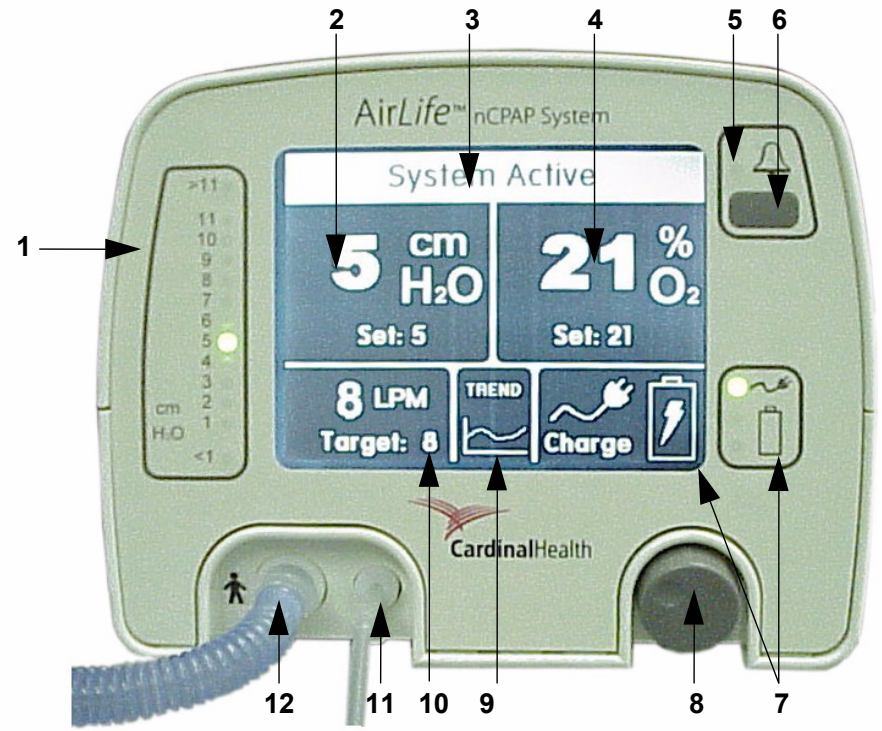


Figure 1: Front Panel Features

Item	Description
1	Pressure LED Bar Graph (Indicates instantaneous patient pressure)
2	Pressure Display (Indicates average patient pressure)
3	Message Bar
4	FiO_2 Display
5	Alarm Priority LEDs and Alarm Mute
6	Alarm Mute/Reset Button (Press & Release for Mute/Reset; Press & Hold for Standby Mode)
7	Power Status
8	Interface Control Knob
9	Trend Selection
10	Flow Display
11	Pressure Line Connection
12	Patient Connection

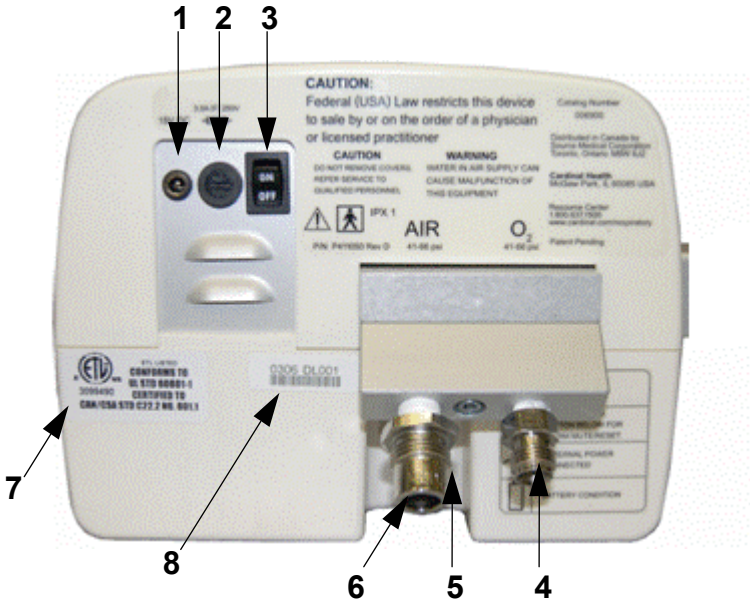


Figure 2: Back Panel Features

Item	Description
1	Power Connection
2	Fuse
3	Power Switch (Switch does not disconnect driver from main power supply)
4	Oxygen Inlet
5	Water Trap and Air Filter (behind Air Inlet; not visible in this view)
6	Medical Air Inlet
7	Nationally Recognized Testing Laboratory (NRTL) Classification
8	Serial Number

Warnings and Cautions Summary

The Air*Life*® nCPAP System Driver is intended to be operated only by qualified personnel under the direction of a physician. The operator is responsible for reading and thoroughly understanding the provided product documentation.

Definitions to be considered throughout the document:

> ***Warning: Used when the operator or the patient have the possibility of being injured.***
>
> Caution: Used when the driver or accessories used with the driver have the possibility of being damaged.
>
> *Note:* Used for statements that could allow for more efficient or convenient operation or service of the equipment.

The following are warnings, cautions, and notes that will appear within this document. Please become familiar with their content.

Warning: The patient accessories for use with the* Air*Life*® *nCPAP Driver are for single patient use only. Disposable accessories include generators, fixation device, prongs, masks, heated wire breathing circuits, and humidification chambers. DO NOT STERILIZE OR REUSE.

Warning: The driver should only be used after qualified personnel or a technician has authorized it for use.

Warning: Oxygen vigorously accelerates combustion. To avoid an explosion hazard, do not use any instrument or piece of equipment that may have been exposed to oil or grease contamination.

Warning: To avoid the risk of fire or explosion, use this device in well-ventilated areas away from flammable anesthetics.

Warning: When driver is connected to power source, keep cords clear of walkways to avoid possible cord entanglement and strangulation.

Warning: Use this product only as directed in the product literature to reduce the possibility of nasal and skin irritation, and necrosis.

Warning: There is always a risk when using oxygen that the O_2 level in the arterial plasma will reach an unacceptable level. This driver should always be used in conjunction with a pulse oximeter to monitor patient status. Oxygen toxicity can be a concern with this device for the intended population if it is used for more than a few hours. Risks include:

- ***Absorption atelectasisi (collapse of lung tissue)***
- ***Hypercapnia (increased carbon dioxide)***
- ***Retrolental hyperplasia (which can cause blindness)***

Also, Chemotherapy patients given bleomycin appear to be extremely sensitive to even relatively low levels of oxygen.

Warning: The use of any power cords with the* AirLife® *nCPAP System Driver other than those supplied with the driver may result in increased emissions and/or decreased Immunity of the* AirLife® *nCPAP System Driver.

Caution: Although the AirLife® nCPAP System Driver meets the requirements of current EMC/RFI legislation, this does not guarantee immunity from all sources of radiated energy. Some mobile telephones and other products containing radio transmitting components may cause malfunction of the AirLife® nCPAP System Driver and should not be used in the vicinity of the driver.

Caution: Federal (USA) law restricts sale of this driver to, or on the order of, a physician.

Caution: Any liquid introduced into the gas supplies will cause malfunction of this driver and the equipment connected to it.

Caution: This driver is designed to mix oxygen and air only. Do not alter the inlets for any other gas sources, such as anesthesia gases.

Caution: The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC adapter from either the driver or the AC outlet.

Caution: The correct AC adapter must be used with the driver. Use of an incorrect AC adapter can damage the internal circuits of the driver.

Caution: Using the driver without the proper filters can allow dirt or moisture to enter the system. This will damage the electronic blender, leaving the unit non-operational.

Caution: Ensure that the driver is unplugged from external power and that the power switch is in the “Off” position before cleaning.

Caution: The driver will be damaged if any part of it is immersed in liquid or gas, or steam sterilized.

Note: Alarms are delayed for 120 seconds after entering the main screen in order to allow time for patient setup. If the patient setup takes longer than 120 seconds, the alarms can be muted for an additional 120 seconds by pressing the alarm mute/reset button or the system can be placed into Standby Mode.

Note: To enhance patient safety and comfort, use only with heated humidifiers and heated wire circuits. The recommended setting is 37 °C, 100% RH.

Note: To obtain maximum battery life, it is recommended that the driver remain connected to an external power source even when it is not in use.

Note: Class 1 LED product.

Note: Hospital personnel should keep records of Performance Verification Tests and identify equipment that is authorized for use.

Note: The Driver must have both gases properly connected and within the specified pressure range in order to pass the initial start-up sequence. This will enable the Driver to perform a valid calibration and ensure accurate FiO_2 delivery.

Operating Instructions

The Air*Life*® nCPAP System is designed to provide an airway pressure that is practically constant. The Air*Life*® generator utilizes vortice technology to help reduce the patient's imposed Work of Breathing. The Driver automatically adjusts the gas flow rate to deliver the set CPAP level and compensate for minor leaks in the system.

Caution: Federal (USA) law restricts sale of this driver to, or on the order of, a physician.

Warning: The driver should only be used after qualified personnel or a technician has authorized it for use.

Warning: Oxygen vigorously accelerates combustion. To avoid an explosion hazard, do not use any instrument or piece of equipment that may have been exposed to oil or grease contamination.

Warning: To avoid the risk of fire or explosion, use this device in well-ventilated areas away from flammable anesthetics.

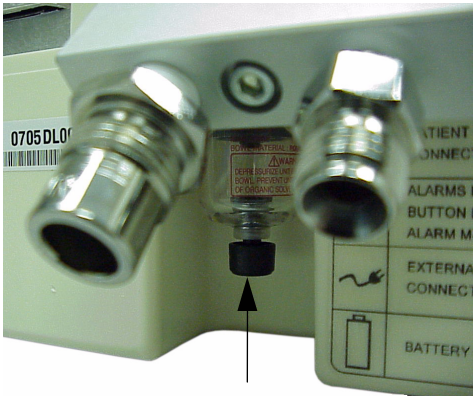
Driver Setup

1. Securely attach the driver to a stand or other mounting system that includes a heater/humidification system. See Figure 3. A mounting plate is included with the Driver and should be attached to the driver using the supplied hardware. Ensure that the stand is rated to safely handle the weight and dimensions of the driver, as detailed in "Product Specification" on page 3.

Figure 3: The Driver Attached to a Stand

Note: To enhance patient safety and comfort, use only with heated humidifiers and heated wire circuits. The recommended delivery is 37 °C, 100% RH.

2. Visually inspect the inlet air filter and water trap, located on the back of the driver. See Figure 4. If the filter is dirty or wet, it must be cleaned or replaced. A tool is included with the driver to assist in removing the water trap.



Air Filter and Water Trap

Figure 4: Location of Air Filter and Water Trap

Caution: This driver is designed to mix oxygen and air only. Do not alter the inlets for any other gas sources, such as anesthesia gases.

Caution: Any liquid introduced into the gas supplies will cause malfunction of this driver and the equipment connected to it.

Caution: Using the driver without the proper filters can allow dirt or moisture to enter the system. This will damage the electronic blender, leaving the unit non-operational.

3. Connect medical air and oxygen hoses to the back of the driver. See Figure 5. Then connect the hoses to their respective high-pressure sources.

   Note: The Driver must have both gases properly connected and within the specified pressure range in order to pass the initial start-up sequence. This will enable the Driver to perform a valid calibration and ensure accurate FiO_2 delivery.

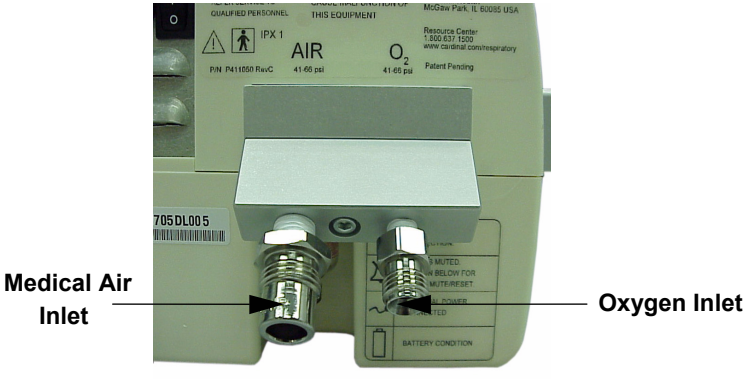


Figure 5: Air and Oxygen Connectors on Driver

- Plug the external power source into the power connector on the back of the driver and an AC outlet. See Figure 6.

Figure 6: AC Power Connector on Driver

Warning: When driver is connected to power source, keep cords clear of walkways to avoid possible cord entanglement and strangulation.

Note: To obtain the maximum battery life, it is recommended that the driver remain connected to the power source even when not in use.

5. Power on unit and verify that all of the LEDs illuminate. See Figure 7.

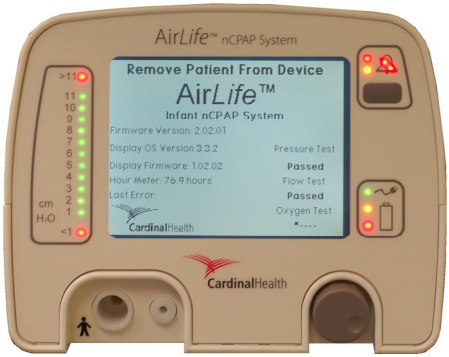


Figure 7: Illuminated LEDs

Note: Class 1 LED product.

6. Verify that the following default values are indicated on the main screen:
   - ***CPAP Set: 5 cmH_2O***
   - ***FiO_2 Set: 21% O_2***
   - ***Flow Rate Target: 8 LPM***
   - ***Battery charging (lightning bolt in battery icon)***

   Note: Alarms are delayed for 120 seconds after entering the main screen in order to allow time for patient setup. If the patient setup takes longer than 120 seconds, the alarms can be muted for an additional 120 seconds by pressing the alarm mute/reset button or the system can be placed into Standby Mode. See Figure 8.

Figure 8: Alarm Mute/Reset Button

7. Unplug external power, verify a single audible alarm burst sounds and the interface indicates the driver is operating on battery power. Plug external power source back in.

   Caution: The power switch does not disconnect the driver from the main power supply. This can only be accomplished by disconnecting the AC adapter from either the driver or the AC outlet.

Interaction with Display Settings

Control of the various Air*Life*® nCPAP Driver features is accomplished through the use of the Interface Control Knob.

Figure 9: Interface Control Knob

Interface Control Knob Operation

To adjust the $\%O_2$, CPAP, or Flow Target values, follow these steps.

1. Rotate the knob to move the highlight cursor to the different sections of the screen. See Figure 10. The default location for the highlight cursor is the Set $\%O_2$.

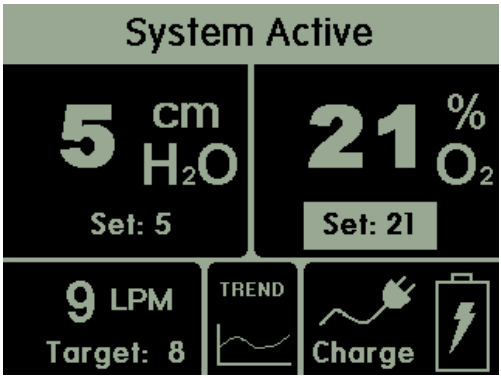


Figure 10: Main Display Screen

2. Select the parameter by pressing the knob when the section you wish to change is highlighted.
3. A prompt will appear in the Message Bar at the top of the display showing the current settings for that feature. Rotate the knob clockwise to increase the value, counter-clockwise to decrease the value.

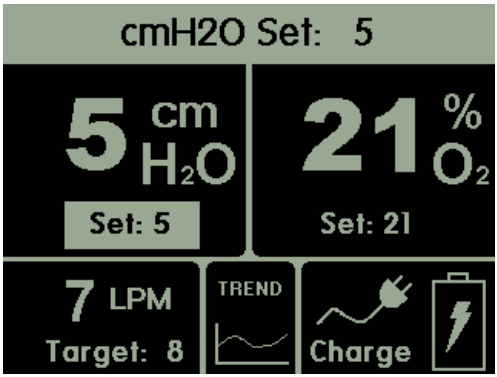


Figure 11: Parameter Change Screen

When the desired value is displayed in the Message Bar, press the knob and release to activate the new set value. The value will set only on the release, not the press, of the knob. The change will automatically be canceled after ten (10) seconds of inactivity and the previous setting will remain unchanged.

4. The flow rate displayed on the LCD screen indicates the flow rate exiting the patient outlet port. The "Target" flow is pre-set based on the CPAP setting. The flow is automatically adjusted to maintain the CPAP setting and it may normally vary from the Target flow.

5. The Driver will automatically increase flow up to 3 lpm above the Target flow to compensate for normal leaks (i.e. leaks around prongs, masks, or through the patient's mouth).

    • If a large leak exists at the patient, and cannot be corrected by adjusting the patient interfaces, then the Target flow may be set higher (up to 13 lpm) to provide more flow to compensate for leaks. If the leak is resolved, the Driver will automatically reduce the flow to maintain the set CPAP level.

    • The flow rate should not be less than 3 lpm. A "low flow" alarm will activate if the measured flow rate is less than 3 lpm and would indicate a possible occlusion of the expiratory limb or a defective circuit / generator. If this alarm occurs, check for pinched or kinked tubing, or replace the circuit and / or generator.

Standby Mode

The Air*Life*® nCPAP System Driver has a Standby Mode to allow the operator to mute the alarms for up to 20 minutes while at the bedside attending to the patient. The mode is selected by pressing and holding the Alarm Mute/Reset button until there is a single audible burst (approximately 3 seconds). The operator can exit the mode by pressing the Alarm

Mute/Reset button or the system will automatically exit the mode and resume normal operation after 20 minutes. While in Standby Mode the system will operate normally with all audible alarms muted, with the exception of High Pressure and Low Flow. To indicate that the system is in Standby Mode, the Message Bar will display “Standby Mode” and the Alarm Mute Leeds will flash. There will also be a single audible burst every two (2) minutes while in Standby Mode. The driver will exit Standby Mode automatically if a High Pressure or Low Flow alarm occurs.

Air or Oxygen Only Mode

While switching Air and Oxygen supply hoses from one source to another (e.g. switching from tanks to wall sources), change one source at a time. This will help prevent interruptions in fresh gas flow to the patient. The Air*Life*® nCPAP System Driver may be used with a single gas source if one gas source goes outside of the specified range (e.g. running out of gas) during normal operation. During such an event, the Driver will alarm and display the source fault in the Message Bar. In the absence of one gas source, the patient can only receive air (FiO_2 ~ 21%) or Oxygen (FiO_2 = 100%). If the fault cannot be corrected immediately, then the user may select “Air Only” or “Oxygen Only” operation in order to mute the alarm while the faulty gas source is corrected. When the faulty source pressure is corrected, the system will automatically return to normal operation (alarms will be delayed for 20 seconds) and blend gases to the previous set FiO_2 value.

Trending

The Air*Life*® nCPAP System Driver has a trend screen. This screen will display data for the previous 4, 8, 12, or 24 hours. Traces are displayed simultaneously on the screen, see Figure 12. The trending screen will allow the operator to know if there have been any fluctuations in the displayed parameters. Information stored for the previous patient is automatically removed when the unit is powered up.

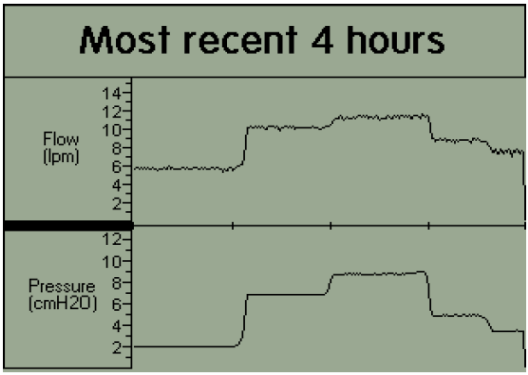


Figure 12: Trending Display on Screen

To access the Trend screen:

1. Rotate the interface control knob until the 'Trend' feature is highlighted.
2. Press and release the knob to activate the Trend screen.
3. Rotate the knob to select the desired Trending time: 4, 8, 12, or 24 hours. The data that is displayed is not actively updating.
4. Press and release the knob to return to the main display. The system will also exit the Trend screen if an alarm condition occurs or after 120 seconds of inactivity.

System Operation

Follow manufacturer's recommended instructions when setting up a patient with the fixation device, generator and patient interface.

Once the patient has been properly set-up, set the prescribed values for the CPAP level and FiO_2. Connect the pressure line and the drive line of the circuit to the driver. See Figure 13.

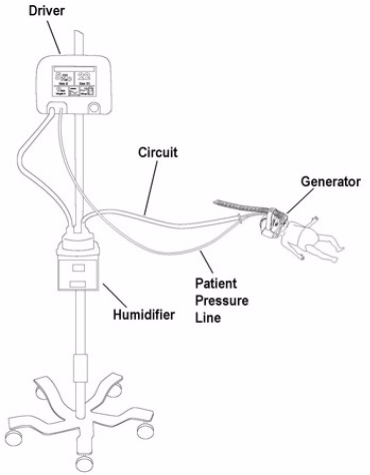


Figure 13: Typical Driver Setup

If an alarm occurs during operation, it should be addressed immediately to ensure that the patient is receiving the proper therapy. Details about the alarms generated by the driver are listed in the Alarm details and actions section of this manual. Medium Priority alarms are self-clearing when the corresponding fault condition no longer exists. High Priority alarms are not self-clearing and must be manually reset by the operator.

Due to the nature of the treatment, operators must know and understand all of the potential hazards and complications that can arise during use of this driver. To ensure safe and effective treatment and use of this driver, the operator must use all necessary precautions. These precautions include, but are not limited to the following:

- ***Properly apply fixation device and generator***
- ***Ensure proper prong/mask size***
- ***Inspect the patient every four (4) hours for the following:***
  - Nasal irritation and septal distortion
  - Skin irritation and pressure necrosis
  - Nasal mucosal damage due to lack of humidification
  - Gastric insufflation and abdominal distension

Warning: Use this product only as directed in the product literature to reduce the possibility of nasal and skin irritation, and necrosis.

Warning: There is always a risk when using oxygen that the O_2 level in the arterial plasma will reach an unacceptable level. This driver should always be used in conjunction with a pulse oximeter to monitor patient status. Oxygen toxicity can be a concern with this device for the intended population if it is used for more than a few hours. Risks include:

- ***Absorption atelectasisi (collapse of lung tissue)***
- ***Hypercapnia (increased carbon dioxide)***
- ***Retrolental hyperplasia (which can cause blindness)***

Also, Chemotherapy patients given bleomycin appear to be extremely sensitive to even relatively low levels of oxygen.

Final Checks and Routine Inspection

Inspect the system after set-up and routinely, at least every four (4) hours, to ensure the proper fit and function of the device by checking the following:

1. Ensure that the patient is receiving the intended CPAP level and FiO_2.
2. Observe the flow rate and verify that it is within 3 LPM of the Target Flow. If not, inspect and readjust the equipment (generator, fixation device, etc.) to ensure a good seal with the patient's nose.
3. Ensure no deformation or irritation to the nose or surrounding tissue is observed.
4. When using prongs, ensure that the proper size is being used. The patient's septum should be clearly visible without having to move the generator.
5. When using masks, ensure that the patient's eyes are clearly visible and that the nares are not blocked.
6. Inspect the fixation device and straps for proper tension and adjust as needed to maintain a proper fit. Use the least tension possible to maintain stability. Do not over-tighten the straps.
7. Ensure that the straps are not twisted.
8. Frequently inspect the skin at all contact points on the nose and head for irritation. Gently massaging the areas of contact may help stimulate circulation.
9. Ensure that the patient's ears are not folded beneath the fixation device.
10. Inspect for nasal mucosal damage due to lack of humidification.
11. Monitor the patient for gastric insufflation and abdominal distension (possible with any nasal CPAP delivery system).

12. If running in battery mode, ensure that the battery is sufficiently charged.

Icon Legend

Figure 14, below, describes the meanings of the different icons that may appear on the driver display.

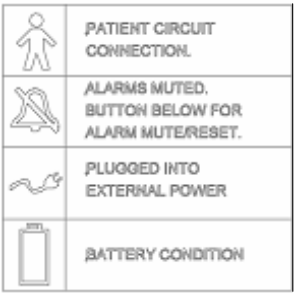

PATIENT CIRCUIT CONNECTION.
ALARMS MUTED. BUTTON BELOW FOR ALARM MUTE/RESET.
PLUGGED INTO EXTERNAL POWER
BATTERY CONDITION

Figure 14: Icon Legend

Alarm Details and Actions

Alarm	Priority	Indication	Suggested Action
Elevated Pressure (2cm H_2O over Set Value)	Medium	• Audible alarm • Yellow flashing LED • Message Bar	• Check the exhaust tube for occlusions or restrictions
Low Pressure (2cm H_2O under Set Value)	Medium	• Audible alarm • Yellow flashing LED • Message Bar	• Check for leaks in the tubes and circuit, or in the nasal prongs and mask • Check supply gasses • Ensure that Auxiliary flow is not set higher than the values in Table 1.
High Pressure (≥12 cm H_2O for 2 seconds or ≥18 cm H_2O instantaneously)	High	• Audible alarm • Red flashing LED • Message Bar • The patient delivery valve closes and a relief valve opens immediately upon alarm. System attempts to reinitiate treatment every three (3) seconds until the alarm condition clears.	• Check the exhaust tube for occlusions or restrictions
Disconnect (Table Based)	Medium	• Audible alarm • Yellow flashing LED • Message Bar • The flow rate is adjusted to Target Flow ±2 LPM.	• Check for leaks or disconnections in the tubes and circuit, or in the nasal prongs and mask.
% O_2 Alarms (Utilizes an oxygen time product. Time product is defined as: the variance from FiO_2 set point multiplied by the amount of time of the variance.)	Medium (20 %O_2 * sec)	• Audible alarm • Yellow flashing LED • Message Bar	• Check Supply Gasses • Restart driver to perform oxygen sensor calibration
	High (30 %O_2 * sec)	• Audible alarm • Red flashing LED • Message Bar.	• Check supply gasses • Restart driver to perform oxygen sensor calibration

Alarm	Priority	Indication	Suggested Action
Leak (3 LPM over the Target Flow rate or a Flow Rate of >15 LPM)	Medium	• Audible alarm • Yellow flashing LED • Message Bar	• Check for leaks or disconnections in the tubes and circuit, or in the nasal prongs and mask • If leak can not be corrected by re-positioning or re-sizing the patient interface, the Target flow can be increased to allow the driver to deliver higher flows when necessary.
Low Flow (At or below 3 LPM flow rate)	High	• Audible alarm • Red flashing LED • Message Bar	• Check the exhaust tube for occlusions or restrictions
External Power Disconnect	Low	• Single audible burst • Indicator on display • LED turns off	• Plug in external power
Battery Low Dual Stage Alarm	Medium (~24 minutes remaining)	• Audible alarm • Yellow LED	• Plug in external power
Battery Low Dual Stage Alarm Battery Charge Fault	High (~12 minutes remaining)	• Audible alarm • Red Flashing LED • Message Bar	• Plug in external power
	High	• Single Audible burst • Red Power LED • LCD indicator	• System will be required to have external power connected to ensure patient treatment is not interrupted.
Oxygen Pressure Low	High	• Audible alarm • Red Flashing LED • Message Bar	• Correct oxygen supply pressure • Select ‘Air Only’ mode • Follow on-screen directions
Oxygen Pressure High	High	• Audible alarm • Red Flashing LED • Message Bar	• Correct oxygen supply pressure • Select ‘Air Only’ mode • Follow on-screen directions

Alarm	Priority	Indication	Suggested Action
Air Pressure Low	High	• Audible alarm • Red Flashing LED • Message Bar	• Correct air supply pressure • Select 'Oxygen Only' mode • Follow on-screen directions
Air Pressure High	High	• Audible alarm • Red Flashing LED • Message Bar	• Correct air supply pressure • Select 'Oxygen Only' mode • Follow on-screen directions
Oxygen Sensor Calibration Error	High	• Audible alarm • Red Flashing LED • Calibration Error Screen	• Follow on-screen directions • While alarm is active, the driver provides CPAP and FiO_2; however, the FiO_2 may not be accurate. • Remove patient from device and restart driver
Flow / Pressure Sensor Failure	High	• All LEDs illuminated • Sensor Calibration Failure screen	• Make sure Patient is disconnected from circuit and restart driver. • Follow on-screen directions
Software Fault	High	• Audible alarm • Red Flashing LED • Message Bar	• Record the Fault code • Follow on-screen directions

Cleaning and Routine Maintenance

Routine maintenance and cleaning should be performed every six (6) months or if a driver fails the Driver Setup procedure. However, maintenance can be performed as often as desired. A unit that fails must be removed from service for a complete service or calibration inspection.

Note: Hospital personnel should keep records of Performance Verification Tests and identify equipment that is authorized for use.

The battery included in the driver requires no routine maintenance. The driver should remain connected to the external power whenever possible to ensure a full charge in case patient transport is necessary and to achieve the expected, useful battery life of two (2) years.

Caution: The correct AC adapter must be used with the driver. Use of an incorrect AC adapter can damage the internal circuits of the driver.

Unit Inspection and Cleaning

1. Visually inspect the inlet air filter and filter bowl. If the filter is dirty or wet, it must be replaced. A tool is included in the accessories box to assist in the removal of the filter bowl.

   Caution: Using the driver without the proper filters can allow dirt or moisture to enter the system. This will damage the electronic blender, leaving the unit non-operational.

2. Clean external surfaces with a mild soap or disinfectant. DO NOT USE ABRASIVE CLEANERS.

   Caution: Ensure that the driver is unplugged from external power and that the power switch is in the “Off” position before cleaning.

   Caution: The driver will be damaged if any part of it is immersed in liquid or gas, or steam sterilized.

3. Connect medical air and oxygen hoses to the back of the driver. Then connect the hoses to their respective high-pressure sources. Plug the external power source into the back of the driver and an AC outlet.
4. Observe that all of the LEDs illuminate when the unit is powered up.
5. Verify that the following default values are on the main screen:
   - CPAP Set: 5 cmH_2O
   - FiO_2 Set: 21% O_2
   - Flow Rate Target: 8 LPM
   - Battery charging (lightning bolt in battery icon)

6. Unplug the external power source, verify a single audible alarm burst sounds and the interface indicates the driver is operating on battery power. Indication on the display includes the green LED and Plug icon ceasing to illuminate and bars appearing in the battery to indicate the level of available battery life.
7. Set the $\%O_2$ to 60%, the CPAP Level to 7 cmH_2O, and occlude the nasal prongs.
8. Allow approximately twenty (20) seconds for the valves to adjust and verify that the CPAP reading is at 7 ±1 cmH_2O and that the oxygen concentration is 60 ±3 percentage points.
9. 'High Pressure' alarm test
    - Remove the exhaust tubing from the exhaust port of the generator.
    - Occlude the prongs and set the CPAP level to 5 cmH_2O. Allow approximately twenty (20) seconds for the valves to stabilize.
    - Occlude the exhaust port and verify that the pressure and flow immediately go to zero and a 'High Pressure' alarm activates. After three (3) seconds, flow will reinitiate.
    - Remove the occlusion from the exhaust port and allow approximately 10 seconds for the valves to stabilize. Verify CPAP level is at 5 ±1 cmH_2O.
    - Press the Alarm Mute/Clear button to clear the 'High Pressure' alarm.
    - Replace the exhaust tubing into the exhaust port.

10. 'Disconnect' alarm test
    - Occlude the prongs and set the CPAP level to 5 cmH_2O. Allow approximately twenty (20) seconds for the valves to stabilize.
    - Remove the occlusion of the prongs.
    - Ensure that a 'Disconnect' or 'Low Pressure' alarm activates.
    - If a 'Disconnect' alarm is active, verify that the flow is within ±2 LPM of Target Flow.
    - If a 'Low Pressure' Alarm is active, verify that the flow does not exceed 3 LPM over Target Flow.
    - Occlude the prongs and verify that the CPAP level returns to 5 ±1 cmH_2O within ten seconds.
    -
11. Throughput and trending test
    - Occlude the prongs and set the Target Flow to 13 LPM. Remove the patient Pressure Line to generate Disconnect and Low Pressure alarms. Allow approximately twenty (20) seconds for the valves to stabilize.
    - Verify that the Driver flow reading is between 13 ±2 LPM.
    - Select "TREND" and verify that the Trend Screen Activates.

Disposal

Patient accessories, including the generator, fixation device, prongs, masks, breathing circuit, and humidification chamber, should be disposed of by incineration in order to reduce the risk of contamination.

> ***Warning: The patient accessories for use with the* AirLife® *nCPAP Driver are for single patient use only. Disposable accessories include generators, fixation device, prongs, masks, heated wire breathing circuits, and humidification chambers. DO NOT STERILIZE OR REUSE.***

The battery and LCD display must be disposed of according to local regulations.

Appendix A: Approved Accessories

Component	Company	Catalog Numbers
Disposable Accessories		
Delivery Circuit	Cardinal Health	RC51-12002
	EME/Viasys	CC8112E
	Hamilton	33078
	Fisher and Paykel	RT132
Generator Set (Nasal Prongs are included with the Generator Set)	Cardinal Health	006905
	EME/Viasys	D350T/R, D350T
	Hamilton	33201
Nasal Mask	Cardinal Health	006925, 006930, 006935
	EME/Viasys	D360XS, D360XL, D360XXL
	Hamilton	37700, 37701, 37702
Reusable Accessories		
Heated Humidifier	Fisher and Paykel	MR730, MR850
Driver Stand w/ extension pole & basket	Cardinal Health	006995
Stand Power Strip		006996
Stand Tank Holder		006997

Appendix B: Electromagnetic Compatibility

The following information is directed by the Standard IEC 60601-1-2:2001 for Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

Warning: The use of any power cords with the* Air*Life*® *nCPAP System Driver other than those supplied with the driver may result in increased emissions and/or decreased Immunity of the* Air*Life*® *nCPAP System Driver.

Table 2: Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The Air*Life*® nCPAP System Driver is intended for use in the electromagnetic environment specified below. The customer or user of the Air*Life*® nCPAP System Driver should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance
CISPR 11 RF Emissions	Group 1	The Air*Life*® nCPAP System Driver uses RF energy only for its internal function. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
CISPR 11 RF Emissions	Class B	The Air*Life*® nCPAP System Driver is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonic Emissions	Not Applicable	
IEC 61000-3-3 Voltage Fluctuations, Flicker Emissions	Not Applicable	

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The Air*Life*® nCPAP System Driver is intended for use in the electromagnetic environment specified below. The customer or user of the Air*Life*® nCPAP System Driver should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment—Guidance
IEC 61000-4-2 Electro-Static Discharge (ESD)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-4 Electrical Fast Transient, Burst (EFT) (Note 2)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5 Power Line Surge (Note 2)	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
IEC 61000-4-8 Power Frequency Magnetic Field (50/60 Hz)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-11 Voltage Dips, Short Interruptions, and Voltage Variations (Note 2)	<5 % UT (Note 1) (>95 % dip in UT) for 0.5 cycle	<5 % UT (>95 % dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Air*Life*® nCPAP System Driver requires continued operation during power mains interruptions, it is recommended that the Air*Life*® nCPAP System Driver be powered from a non-interruptible power supply or a battery.
	40 % UT (60 % dip in UT) for 5 cycles	40 % UT (60 % dip in UT) for 5 cycles	
	70 % UT (30 % dip in UT) for 25 cycles	70 % UT (30 % dip in UT) for 25 cycles	
	<5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 5 sec	

Note 1—UT is the AC mains voltage prior to application of the test level.
Note 2—Performed with an Input Voltage of 120 V AC only.

Table 4: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The Air*Life*® nCPAP System Driver is intended for use in the electromagnetic environment specified below. The customer or user of the Air*Life*® nCPAP System Driver should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Air*Life*® nCPAP System Driver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
IEC 61000-4-6 Conducted RF	3 V rms 150 kHz to 80 MHz	3 V rms	$d = 1.2\sqrt{P}$
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz E_1 $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[a] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

b. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be theoretically predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the Air*Life*® nCPAP System Driver is used exceeds the applicable RF compliance level above, the Air*Life*® nCPAP System Driver should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Air*Life*® nCPAP System Driver.

c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 5: Recommended separation distances between portable and mobile RF communications equipment and the Air*Life*® nCPAP System Driver

The Air*Life*® nCPAP System Driver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or user of the Air*Life*® nCPAP System Driver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Air*Life*® nCPAP System Driver, as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix C: Warranty Information

Warranty

This is the standard warranty for the Air*Life*® nCPAP System Driver and is extended only to the buyer purchasing the said product directly from Cardinal Health, Inc. (hereinafter referred to as Cardinal Health) or from an authorized dealer, distributor, or agent as new merchandise.

The Air*Life*® nCPAP System Driver is warranted for a period of two years (24 months) from the date of delivery to be free from manufacturing defects and to conform to the description thereof contained in the relevant Operation and Routine Maintenance Manual.

Cardinal Health's sole obligation under this warranty is limited to the replacement or repair of the product or parts thereof which upon examination are found to contain manufacturing defects or not to conform to the description thereof contained in the relevant manual. Cardinal Health will not be liable for consequential damages.

The foregoing warranty shall not apply if the product or any part thereof has (i) been repaired or altered by anyone other than an authorized representative of Cardinal Health without written consent (ii) subjected to abuse, misuse, negligence or accident (iii) operated under conditions other than normal use (iv) the prescribed periodic maintenance and/or services have not been performed as specified in the relevant manual.

There are no warranties that extend beyond this warranty and the description of the products contained in the relevant Operator's & Routine Maintenance Manual. Cardinal Health makes no warranty as to merchantability with respect to the products. This warranty is given in addition to statutory warranty and in no way affects the purchaser's statutory rights.

Disclaimer

The Cardinal Health guarantee will only be effective on condition that the product is used for the specific intention for which it was designed and operated as given in the Operator's & Routine Maintenance Manual. Any reuse of single use products, or use of the equipment in conjunction with, or while attached to non-approved equipment will automatically void any guarantee or warranty in force. Cardinal Health will not accept any liability for any injury or damage to persons or property resulting from a breach of these conditions. Cardinal Health will only guarantee product supplied if it has been serviced in accordance with procedures given in the Service Manual, by hospital service personnel or authorized representatives who have been trained by Cardinal Health and providing that the product has not been modified, altered or changed unless specifically authorized to do so in writing by Cardinal Health.